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EXAMINER	
PROCTOR, JASON SCOTT	

ART UNIT	PAPER NUMBER
2123	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/679,725	WHIRLEY ET AL.	
	Examiner	Art Unit	
	JASON PROCTOR	2123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-27,29-39,41,42,54-65,67-81,83-94,96-98 and 112-125* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-27,29-39,41,42,54-65,67-81,83-94,96-98 and 112-125* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/19/08, 1/21/09*.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-127 were rejected in the Office Action entered on 18 September 2008.

Applicants' response submitted on 17 February 2009 and supplemental response submitted on 10 March 2009 have amended claims 1, 16, 31, 54, 70, 86 and 124-125; and canceled claims 126-127. Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-125 are pending in this application.

Claims 1-12, 14-27, 29-39, 41, 42, 54-65, 67-81, 83-94, 96-98, and 112-125 are rejected.

Information Disclosure Statements

1. The information disclosure statement filed 19 September 2008 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

2. The information disclosure statement (IDS) submitted on 21 January 2009 was filed after the mailing date of the Office Action on 18 September 2009. The submission is in compliance

with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Response to Remarks – 35 USC § 103

3. Regarding the previous rejection of claims 1-3, 5-7, 9-10, 14, 112-113; 16-18, 20-22, 24-25, 29, 114-115; 31-37, 41, 116-117; 54, 56, 58-60, 62-63, 67-68, 118, 126-127; 70, 72, 74-76, 78-79, 83-84, 124-125; 86, 88-92, 96-97, and 119 under 35 U.S.C. 103(a) as being unpatentable over Rogers in view of St. Ville, further in view of Keane, these rejections are withdrawn for the following reasons.

As discussed in the interview conducted on 26 February 2009, the prior art references relied upon in the previous rejection fail to teach or suggest the presently claimed limitation of "simulat[ing] an interaction between said anatomical feature(s) [of at least one vascular system] and said medical device over at least one dynamic expansion and contraction cycle of the anatomical feature(s) to determine the predicted stresses, strains, and deformations of said medical device due to the interaction of the medical device with the anatomical feature(s)". This limitation or similar language is found in each of the independent claims.

In particular, Rogers teaches simulation of a cardiovascular stent, but is directed primarily to injuries to the artery caused by the stent placement procedure (Rogers, abstract), and does not simulate interactions caused by a dynamic expansion and contraction cycle of the cardiovascular system. Keane teaches a simulation of a bio-transport system (e.g. a cardiovascular system) but is directed primarily to determining "bio-transport dynamics" and

does not simulate interaction between a cardiovascular stent or medical device with an anatomical feature. St. Ville was not previously relied upon for teaching these limitations.

The previous rejections are therefore withdrawn in response to the amended claim language.

Response to Remarks and

Claim Rejections - 35 USC § 112

The previous rejection of claim 124 under 35 U.S.C. § 112, second paragraph, is withdrawn in response to the amendments to that claim.

Regarding claim 125, in response to the claim amendments and remarks, only the grounds for rejection specified below is maintained. The other previous rejections of claim 125 are withdrawn.

The previous rejection of claims 126 and 127 under 35 U.S.C. § 112, second paragraph, is withdrawn in response to the cancellation of those claims.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 125 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 125 recites "an amount of cycles that would meet or exceed the amount of cycles that would be expected in the individual's lifetime." The phrase "the individual's lifetime" lacks antecedent basis. There is no previous recitation in the claims of an "individual".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

5. Claims 1-3, 5-7, 9-10, 14, 15, 112-113; 16-18, 20-22, 24-25, 29, 30, 114-115; 31-37, 41, 42, 116-117; 54, 56, 58-60, 62-63, 67-69, 118; 70, 72, 74-76, 78-79, 83-85, 124-125; 86, 88-92, 96-98, 119, 124, and 125 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Simulation of *in vivo* loading conditions of nitinol vascular stent structures" by F. D. Whitcher in view of US Patent No. 5,594,651 to St. Ville.

Regarding claims 1, 3, 16, 18, 31, 54, 56, 70, 72, and 86, Whitcher teaches a computer system including at least one processor and memory for analyzing medical devices [*"Vascular support structures are an important tool for treating arteriosclerosis.... This paper describes the simulation analysis of vascular support structures (stents), to provide designers with estimates of their* in vivo *structural behavior and fatigue properties."* (abstract); *"The stent-simulation work used relatively simple and inexpensive CAD systems with a high degree of analyst productivity."* (abstract)], comprising:

A stress/strain/deformation analyzer [*"The finite-element material model used in the stent simulation was a Von Mises yield-criterion elastic-plastic model using the ADINA 270node element and mixed displacement-pressure formulation [2]."* (Whitcher, page 1008, "3. Material Model/Element Formulation")] that receives a finite element model or mesh, material properties of an anatomical feature(s) and a medical device, load data on said anatomical feature(s), and/or said medical device [See Fig. 3, Fig. 5 and related description; pages 1008-1009, sections 3-5,

etc.] and simulates an interaction between said anatomical feature(s) and said medical device over at least one dynamic expansion and contraction cycle of the anatomical feature(s) to determine the predicted stresses, strains, and deformations of said medical device due to the interaction of the medical device with the anatomical feature(s) [*"In the arteries, the cyclical difference between systolic and diastolic pressures generates the most significant forces on the stent… The loading conditions for this analysis therefore consider only the preload and pulsatile radial forces on the structure (see Fig. 5)…The stent-size indication matrix was analyzed for worst-case fatigue conditions. The maximum arterial cyclic expansion due to systolic/diastolic pressure differentials is 5% [6]. The mean stress loading will be highest in a calcified lesion, in which case the cyclic loading will be small as the Young's modulus of calcific plaque is two orders of magnitude higher than that of either healthy tissue or fibro-fatty plaque. In a compliant vessel, the vessel will expand in response to the stent expansion force, reducing the mean stress. The composite structure will be less compliant in systolic/diastolic loading, resulting in lower cyclic strains."* (page 1009, "5. Boundary and Loading Conditions", "6. Fatigue Analysis")].

Whitcher teaches a generated geometric model of said anatomical feature(s) and a mesh model of a medical device [See Fig. 3, Fig. 5; page 1009, "5. Boundary and Loading Conditions"; etc.].

St. Ville teaches a geometry generator that receives three-dimensional volumetric data of at least one anatomical feature(s) and generates a geometric model of said anatomical feature [*"First, a finite element model of the normal bone geometry … is created."* (column 16, lines 44-45); *"For example, the initial geometric model in the case of a prosthetic hip can be generated*

by X-raying a cadaveric hip using, for example, a Siemens Somatom DR3 or a GE 9800 CT scanner. This image data may be converted to a format usable by the CAD software package or may be converted to a format usable by finite element software package (for example, a PDA-PATRAN (available from PDA Engineering) format) to be described below." (column 9, lines 31-38)]; and

A mesh generator that receives said geometric model of said anatomical features and a geometric model of a medical device, and generates a finite element model or mesh representing both of said geometric model of said anatomical features and said geometric model of said medical device [*"A finite element model is again created, but now includes another layer, namely, the artificial hip embedded in the cancellous bone area."* (column 17, lines 4-6); FIGS. 4A, 4B].

Whitcher and St. Ville are analogous art because both are directed to the application of finite element analysis for *in vivo* prosthetic analysis.

It would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the teachings of Whitcher and St. Ville to arrive at the claimed invention because St. Ville expressly teaches that the methods taught therein quickly produce the required models for analysis [*"The use of such computer aided design software packages permits a geometric model of an object or part to be defined by a user and modified quickly and results in generation of geometry data which can be converted to formats useful in a computer aided manufacturing step and/or to formats useful to a finite element method step, which steps are discussed in greater detail below."* (column 9, lines 22-28); *"For example, the initial geometric model in the case of a prosthetic hip can be generated by X-raying a cadaveric hip... This image*

data may be converted to a format usable by the CAD software package or may be directly converted to a format usable by a finite element software package..." (column 9, lines 31-38)]. Therefore, it would have been obvious to a person of ordinary skill in the art to use the teachings of St. Ville to generate a geometric model and a finite element model or mesh to quickly acquire the necessary models for the simulation method taught by Whitcher.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the teachings of Whitcher and St. Ville to arrive at the invention specified in claim 1.

Claims 16, 31, 54, 70, and 86 recite systems and the methods performed by those systems which are substantially identical to the system of claim 1 or present limitations that have been addressed above. These claims are rejected rationale similar to that given above for claim 1.

Claims 18, 56, and 72 reiterate the limitations of claim 3 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 2, 17, and 32 St. Ville teaches that the geometric model of said anatomical features is an idealized geometric model [*"First, a finite element model of the normal bone geometry ... is created. The stiffness properties of each layer are then defined... These stiffness properties and loads are known quantities which have been published in numerous journals..."* (column 16, lines 44-58)].

Claims 17 and 32 reiterate the limitations of claim 2 which have been addressed above. These claims are rejected rationale similar to that given above for claim 3.

Regarding claims 5-7, 20-22, 33-35, 58-60, 74-76, and 88-90, Whitcher teaches that the prosthesis is an endovascular prosthesis, a stent graft, and a cardiovascular stent (abstract).

Regarding claims 9, 24, 36, 62, 78, and 91, St. Ville teaches that the mesh generator includes three-dimensional finite modeling software [*"Other suitable software packages for generating the finite element model include MSC/NASTRAN [...], ABAQUS [...], and ANSYS [...]."* (column 9, lines 54-59)].

Regarding claims 10, 25, 37, 63, 79, and 92, Whitcher teaches that the stress/strain/deformation analyzer is a non-linear finite element modeling software [*"The analyses presented here were run principally using the ADINA direct solver."* (page 1009, "7. Solution")].

Regarding claims 67, 83, 96, 112, 114, and 116, Whitcher teaches that the stress/strain/deformation analyzer uses a non-linear finite element analysis tool to simulate said stresses strains, and deformations of said medical device [*"The analyses presented here were run principally using the ADINA direct solver."* (page 1009, "7. Solution")].

Regarding claims 14, 29, 41, 68, 84, and 97, Whitcher teaches a visualization tool that receives said simulated stresses, strains, and deformations of said medical device from said stress/strain/deformation analyzer and displays one or more of said stresses, strains, and deformations of said medical device via visual representation [*"FE model output was often manipulated and displayed utilizing the Perl data extraction and manipulation language and the 'gnuplot' data graphics system (Free Software Foundation, Cambridge, MA)."* (page 1008, "2. CAD Interface"); (Figure 3)].

Regarding claims 15, 30, 42, 69, 85, and 98 Whitcher teaches that said visualization tool includes interactive software for visualizing finite element analysis results of three-dimensional grids [*"FE model output was often manipulated and displayed utilizing the Perl data extraction and manipulation language and the 'gnuplot' data graphics system (Free Software Foundation, Cambridge, MA). These tools allowed rapid evaluation of the large FE data sets."* (page 1008, "2. CAD Interface)].

Regarding claims 113, 115, 117, 118, and 119, St. Ville teaches that the simulated stresses, strains, and deformations imposed on said medical device comprise dynamic or quasi-static stresses, strains, and deformations [*"mechanical forces shown in FIGS. 4A and 4B during walking and rising from a chair."* (column 8, lines 25-30)].

Claims 115, 117, 118, and 119 reiterate the limitations of claim 113 which have been addressed above. These claims are rejected rationale similar to that given above for claim 113.

Regarding claim 124, Whitcher teaches long term structural integrity testing of said medical device by recreating a plurality of dynamic expansion and contraction cycles of the vascular system [*"In the Symphony nitinol design, the principal use of the finite-element (FE) calculations is prediction of material fatigue life."* (page 1005, "1. Introduction"); *"The model in consideration indicates peak tensile stresses in the region directly opposite the contact area (see Fig. 6). These values are used for generating data good for a Goodman diagram fatigue analysis. The results accurately predict experimental fatigue test results, both for specimens tested to failure and those tested within the designed operating range."* (page 1011, "8. Results")]. A "Goodman diagram fatigue analysis" is well known to those of ordinary skill in the art for predicting long term structural integrity by recreating a plurality of dynamic expansion and contraction cycles ("alternating stress").

Regarding claim 125, Whitcher teaches that the plurality of dynamic expansion and contraction cycles of the vascular system comprise an amount of cycles that would meet or exceed the amount of cycles that would be expected in the individual's lifetime.

6. Claims 4, 19, 57, and 73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Whitcher in view of St. Ville as applied to claims 1, 16, 54, and 70 above, and further in view of US Patent No. 5,880,976 to DiGioia III et al. (DiGioia).

Whitcher in view of St. Ville does not expressly teach acquiring three-dimensional volumetric data via MRI.

DiGioia teaches several techniques of acquiring structural data of a skeletal structure, including MRI [*"Commonly used tomographic techniques include computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomographic (PET), or ultrasound scanning of the joint and surround structure. The tomographic data from the scanned structure generated by the skeletal data source 13 is provided to the geometric planner 12 for use in producing a model of the skeletal structure."* (column 7, lines 8-14)].

Whitcher in view of St. Ville and DiGioia are analogous art because both are directed to modeling prosthetic implants.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the imaging techniques taught by DiGioia in the modeling system of Whitcher in view of St. Ville because DiGioia expressly teaches how to provide for the proper placement and implantation of the joint components to provide an improved range of motion and usage of the joint following joint reconstruction, replacement, and revision surgery (DiGioia, column 4, lines 50-60).

Claims 19, 57, and 73 reiterate the limitations of claim 4 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 4.

7. Claims 8, 23, 61, and 77 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Whitcher in view of St. Ville as applied to claims 1, 16, 54, and 70 above, and further in view of "Automated Mesh Generation of an Arterial Bifurcation Based upon *In Vivo* MR Images" by Seung Lee et al. (Lee).

Whitcher in view of St. Ville does not expressly disclose that the geometry generator is a software application which generates surface points from the three-dimensional volumetric data, which are then converted into stereolithography, slice files, IGES files or a combination thereof.

Lee teaches methods for creating a CFD mesh of a blood vessel based on in vivo measurements taken by magnetic resonance imagine (abstract). Lee teaches generating 3D-lumen geometry using Mimics (page 1, right column) from MR imaging data (page 1, left and right columns).

Whithcer in view of St. Ville and Lee are analogous art because both are directed to imaging and modeling of anatomy.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to combine the use of MIMICS to interpret MRI data and generate geometry as taught by Lee in the modeling system of Whitcher in view of St. Ville because Lee expressly teaches that "the goal of this study was to develop an automated mesh generation technique based on measurements of *in vivo* lumen geometry using MR," (page 1, left column) and therefore provides an automation solution to that step of the modeling process.

Claims 23, 61, and 77 reiterate the limitations of claim 8 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 8.

8. Claims 11-12, 26-27, 38-39, 64-65, 80-81, and 93-94 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Whitcher in view of St. Ville as applied to claims 9-10, 24-25, 36-37, 62-63, 78-79, and 91-92 above, and further in view of "Computational Mechanics Moves Ahead" by Peter J. Raboin (Raboin).

Regarding claim 11, Whitcher in view of St. Ville does not expressly disclose that the three-dimensional finite modeling software tessellates a geometric model into hexahedron brick elements and quadrilateral shell elements to create the mesh.

Raboin teaches several computational mechanics codes for finite element analysis (page 2 of 13, "Structural Problems, Computer Solutions") including DYNA3D (pages 3-6 of 13, "Two Classes of Codes") and NIKE3D (pages 6-8 of 13, "NIKE3D for Biomechanics") for "studying dynamic, finite deformations, [which] can model the behavior of joint tissues and bones subjected to different loads and joint movement with and without prosthetic implants (pages 6-7 of 13).

Whitcher in view of St. Ville and Raboin are analogous art because both are directed to modeling of prosthetics.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicants' invention to use one of the computational mechanics codes taught by Raboin in the modeling system of Whitcher in view of St. Ville because Raboin expressly teaches that the finite element methods have "powerful versatility" that can model "numerous nonlinear material behaviors" (page 2 of 13) and therefore allow greater flexibility in performing a wider variety of simulations.

Claims 26, 38, 64, 80, and 93 reiterate the limitations of claim 11 which have been addressed above. These claims are rejected for rationale similar to that given above for claim 11.

Claims 12, 27, 39, 65, 81, and 94 have been previously interpreted as recited features inherent in DYNA3D and NIKE3D and are therefore rejected for rationale similar to that given above for claim 11. (See Office Action, 7 February 2006, page 5)

9. Claims 55, 71, 87, and 120-123 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Whitcher in view of St. Ville as applied to claims 54, 70, and 86 above, and further in view of "Failure of All-ceramic Fixed Partial Dentures *in vitro* and *in vivo*: Analysis and Modeling" by J.R. Kelly, J.A. Tesk, and J.A. Sorensen (Sorensen).

Regarding claims 55, 71, and 87, Whitcher in view of St. Ville does not expressly disclose performing a simulation to the point of failure of the medical device.

Sorensen teaches performing a finite element analysis (FEA) of fixed partial denture medical devices (abstract) to the point of failure of the device [*"Weibull failure probability (P_f) calculations, incorporating FEA stress profiles… Observations from failed clinical restorations provided critical guidance in validating a laboratory test and focusing a mathematical failure model."* (abstract); *"Fig. 3 is the finite element solution obtained when the abutment was rigidly fixed…"* (page 1255, right column – page 1256, left column, "Results"); *"Both the* in vitro *test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated."* (page 1257, right column, "Discussion")].

Whitcher in view of St. Ville and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling system of Whitcher in view of St. Ville because Sorensen expressly teaches that "[f]ailed structures provide valuable information for improving the design of components and in

validating laboratory tests and structural models" (page 1253, left column, "Introduction") and thereby improving the effectiveness and reliability of the final designs.

Regarding claims 120-123, Whitcher in view of St. Ville does not expressly disclose performing a failure mode simulation.

Sorensen teaches a geometric model of an *in vitro* failure mode test [*"Figure 4. Finite element solution when the abutment tooth is allowed to rotate… This result corresponds more closely to the fractographic findings* [failure mode] *than does the solution in Fig. 3"* (Fig. 4, caption)].

Sorensen teaches a step of simulating stresses, strains, and deformations imposed on said candidate medical device design in said *in vitro* failure mode test [*"Finite element analysis (FEA) of the laboratory FPDs found that maximum principal tensile stresses would occur at locations consistent with the fractographic observations…"* (abstract)].

Sorensen teaches comparing simulation data generated by said step of simulating and additional simulation data generated by said step of simulating an *in vitro* failure mode test [*"Both the* in vitro *test examined and the mathematical model seem to capture a number of primary features of clinical failure, and as such are at least partially validated."* (page 1257, right column, "Discussion"); *"Fig. 5 is a plot of the probability of failure* vs. *failure load for data from the 20 laboratory FPDs along with calculated failure probabilities based upon the finite element results with abutment rotation allowed. Probabilities for the* in vitro *data were simply evaluated…"* (page 1256, left column, "Results")].

Sorensen teaches that the *in vitro* failure mode test parameters, while not part of the disclosed model, are known in the art and the absence of this influence is a criticism of the disclosed model [*"Possible effects of damage accumulation due to cyclic loading (Suresh, 1991) are also not part of the model. These same criticisms hold for the laboratory test as well."* (page 1257, right column, "Discussion")].

Whitcher in view of St. Ville and Sorensen are analogous art because both are directed to finite element analysis of medical devices.

Therefore it would have been obvious to a person of ordinary skill in the art at the time of Applicant's invention to combine the failure mode tests taught by Sorensen in the modeling system of Whitcher in view of St. Ville because Sorensen expressly teaches that "[f]ailed structures provide valuable information for improving the design of components and in validating laboratory tests and structural models" (page 1253, left column, "Introduction") and thereby improving the effectiveness and reliability of the final designs.

Conclusion

Art considered pertinent by the examiner but not applied has been cited on form PTO-892.

"Critical issues in high cycle fatigue" by T. Nicholas teaches techniques known in the art prior to Applicants' invention for performing a lifetime fatigue analysis including what is "commonly ... referred to as a Goodman diagram or a Modified Goodman diagram" (page S222, "3. Constant life diagrams"). Nicholas teaches plotting "available data ... as alternating stress

versus mean stress for a constant design life, usually 10^7 cycles or higher" (page S222, "3. Constant life diagrams").

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Proctor whose telephone number is (571) 272-3713. The examiner can normally be reached on 8:30 am-4:30 pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paul Rodriguez can be reached at (571) 272-3753. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application should be directed to the TC 2100 Group receptionist: 571-272-2100. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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